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By: Paul Naik

**JEREMY RIFKIN: AN EXAMINATION OF THE EFFORTS OF AN ANTI-BIOTECHNOLOGY
ACTIVIST**

INTRODUCTION

“The biotech revolution will affect every aspect of our lives. The way we eat; the way we date and marry; the way we have our babies, the way our children are raised and educated; the way we work; the way we engage in politics; the way we express our faith; the way we perceive the world around us and our place in it... each of us [will be forced] to put a mirror to our most deeply held values, making us ponder the ultimate question of the purpose and meaning of existence.”¹ In this declaration we see both the tremendous awe with which the promises and power of biotechnology are greeted, and the fear, even trepidation, with which the potential changes it could wrought on human existence is viewed. Therein lies the problem.

“Biotechnology” is broadly defined as “the application of biological systems and organisms to technical and industrial processes.”² This broad category includes the use of cell fusion technology to produce biological entities such as antibodies and the process of genetic engineering. The latter process involves the manipulation of the genetic code of living organisms, primarily through the method of recombinant DNA. It is primarily this ability to control the genetic blueprint that has given rise to the controversies surrounding biotechnology. However, because genetic engineering is so intimately associated with biotechnology generally, and its power is so overwhelming that it has largely supplanted traditional biotechnology methods, much of the opposition against genetic engineering has been directed to biotechnology as a whole.

It would be no exaggeration to say that since its advent about two decades ago, genetic engineering has revolutionized the life sciences and the pharmaceutical industry. The technology, in its various conceptions and applications, is now manifested in a wide range of applications in the agricultural and food industry, in unprecedented medical and healthcare innovations, and in the functional structure of the workplace. The recent report of a breakthrough in cloning of a sheep from an adult cell is a representative discovery that illustrates the wondrous possibilities of this technology.

It is really no wonder that biotechnology in the form of genetic engineering would not be accorded unequivocal acceptance. In the early days of the technique, even some molecular biologists were uncomfortable with the implications of recombining genetic material (DNA). This wariness led to a worldwide moratorium on recombinant DNA experiments in 1973 and 1974. The moratorium was followed in 1975 by a gathering of scientists at the Asilomar Conference Center in Pacific Grove, California, where a set of recombinant DNA research guidelines were produced. At the same time, the public, provoked by anti-biotech activists abetted by an uncritical media, was whipped into a frenzy by claims of accidental outbreaks of infectious cancer and possible release of genetically-modified bacteria from university laboratories.³

The hysteria eventually subsided when it soon became obvious that biotechnology was not about to lead to the apocalypse. However, the same controversies and concerns re-surfaced to dog the biotechnology industry during the 1980's, albeit in less outlandish incarnations, when the first industrial fruits of genetic engineering arrived in the marketplace. At this point, the Food and Drug Administration, which was the agency charged with regulating the foods and drugs sold to the American public, was faced with a difficult task. It had to promulgate rules and policies relating to biotechnology that were to be at once fair to the industry while true to the agency's mission of protecting the health and safety of the people and the environment. This task was confounded by the activities of citizen-activists who disagreed with the agency seemingly at every step of the way. The challenges the FDA faced in dealing with the first genetically engineered commercial products have not abated, and are expected to intensify as we enter a new era of biotechnology.

The capability to clone a viable mammal from an adult cell, and the specter of imminent cloning of human individuals that accompanies it, illustrates how future biotechnology products will likely extend beyond mere genetically engineered versions of presently existing molecules (for instance, genetically engineered version of the naturally-existing hormone insulin). Potential products include germline gene alterations, laboratory-grown body parts, genetically-designed babies and human cloning. As a new wave of biotechnology products is set to enter the marketplace, we will see the re-emergence of the many questions about how much, and whether at all, to permit the development of this technology. And, undoubtedly, the FDA will once again be at the forefront of the battle over how to regulate these products.⁴

This paper attempts retrospectively to examine the impact of the efforts of Jeremy Rifkin on the rules and regulation, and ultimately the mission, of the Food and Drug Administration (FDA) pertaining to biotechnology. Rifkin arguably single-handedly raised the consciousness of the American public, and indeed the world, to the potential risks of the technology, at least as he saw them. In this way, he positioned himself as a biotechnology gadfly who became the bane of the biotechnology industry and federal agencies regulating biotechnology. It seems fitting, therefore, to study the impact of anti-biotechnology activism on federal regulation of biotechnology by focusing on Rifkin's efforts.

In the course of examining Rifkin's activities that were targeted specifically at the FDA, this paper also discusses his efforts aimed at curbing recombinant DNA research regulated by the National Institutes of Health and genetic engineering activities that fell under the jurisdiction of the United States Department of Agriculture (USDA) and Environmental Protection Agency (EPA). The reasons for this are several-fold.

First, regulatory changes in non-FDA federal agencies that have jurisdiction over biotechnology can have a direct impact upon FDA regulations. The FDA, USDA, EPA, NIH, Occupational Safety and Health Administration (OSHA) and National Science Foundation (NSF) are federal agencies that are collectively charged with insuring the safety of biotechnology research and products within a coordinated framework for the regulation of biotechnology.⁵ One of the basic principles of the coordinated framework of regulation is the promulgation of consistent regulatory policies among the agencies.⁶ In this regard, the FDA has demonstrated its adherence to this principle. In some instances, it has adopted the relevant regulations from other agencies within the Coordinated Framework instead of promulgating its own regulations.⁷ Thus, the impact of Rifkin's activities on non-FDA agencies has on occasion extended to the FDA as well.

Second, the FDA's function in ensuring the safety of biotechnology products is dependent on the proper flow of biotechnology products through the research pipeline. The vibrancy of biotechnology research is at least partly dependent on how much regulation is imposed on it by regulatory agencies such as the EPA (e.g., regulation of bio-pesticides) and USDA (e.g., field testing of genetically-modified organisms). Thus, any obstruction of research through increased regulation forced by activists such as Rifkin would impede flow of biotechnology products to the FDA review stage, thus ultimately affecting the FDA's function by limiting the number and variety of products that it gets to assess.

BIOGRAPHY OF JEREMY RIFKIN

Early years

Jeremy Rifkin graduated the Wharton School of Finance at the University of Pennsylvania and the Fletcher School of Law and Diplomacy at Tufts University with a bachelor degree in economics and a master's degree in international affairs, respectively. His social activism began in the 1960s. Among his self-proclaimed accomplishments are helping to organize student opposition to germ-warfare projects at the University of Pennsylvania in 1966 and sponsoring the first national anti-Vietnam War rally in 1967. He later served as national coordinator for the National Committee for a Citizens Commission of Inquiry on U.S. War Crimes in Vietnam. In 1971, he co-founded the radical New American Movement (NAM), which was a leftist political group. Through this movement, Rifkin pushed for the formation of a forum for mass media exposure as a mechanism for raising political awareness and to promote NAM and other radical activities and demands, thus foreshadowing his subsequent skillful engagement of the mass media in his crusade against biotechnology. In 1972, the Peoples Bicentennial Commission (PBC) was born. Through this forum, Rifkin engaged in activities that he characterized as a new American Revolution aimed at creating fundamental changes in social, economic and political institutions. These changes were to include indictment of economic freedoms and the accompanying prosperity. He believed in the elevation of human rights above property values, identifying personal rights with the collective interest. In his view, health care was a human right instead of a market commodity to be sold to the highest bidder – technology was made to serve rather than to exploit man and the environment, and production for profit was to be replaced by production based on human need and peace.⁸

Rifkin exhibited his attention-garnering talent early in his career. His PBC once sent tape recordings to 8,000 wives of America's top corporate executives urging the women to question their husbands about corporate wrongdoing and corruption. It also announced a \$25,000 reward offer to over 10,000 secretaries for information leading directly to the arrest, prosecution, conviction, and imprisonment of chief officials of Fortune 500 corporations for criminal corporate activities.⁹ 5

Following a conspicuous lack of success through the PBC's activities, Rifkin turned his attention to the pharmaceutical industry's experiments with DNA. This switch was accompanied by a change of name for the PBC (which had earlier been changed from the Peoples Bicentennial Commission to the Peoples Business Commis-

At a meeting of molecular biologists at the National Academy of Sciences in 1977, Rifkin made his debut as a high-profile anti-genetic engineering activist by leading a protest that included protesters surrounding the audience during a conference session and the singing of “We shall not be cloned.” Interestingly, the aggressive protest had only an equivocal impact on the conference participants. One of the scientist participants characterized it as “more amusing than threatening.”¹¹ This protest, and the equivocal, almost dismissive, response it received, was to parallel Rifkin’s subsequent activities and the reception of most biotechnology proponents.

In the 1980’s, as a result of his unique brand of anti-biotechnology crusading activities, Rifkin received wide media attention. The media took to viewing him as “the biotechnology revolution’s leading counterrevolutionary”¹² and “biotechnology’s most outspoken critic.”¹³

The substantial amount of attention Rifkin received belied the size of the organization through which Rifkin engaged his gadfly activities, the FET. The FET, at the height of its prominence, consisted of Rifkin, one assistant, one secretary and two lawyers. It did not have members, and ran on a small budget of a couple of hundred thousand dollars annually generated from Rifkin’s speaking fees and the sale of his books.¹⁴ Its stated purpose was, and continues to be, to engage in activities centered around the environmental, ethical and economic concerns raised by the development of emerging technologies.¹⁵

Jeremy Rifkin has been a prolific writer. He is the author of about a dozen books that cover a wide range of topics.¹⁶ In a number of his books, he espouses his conception of the world, and, relatedly, how technological changes would affect it. In “Entropy,” he discusses the synthesis of environmental and economic theory while seeking to lay the groundwork for notions of sustainable development.¹⁷ In “Who Should Play God?,” he (and co-author) plainly voices his opposition to genetic engineering, claiming the technology would be as deadly as a nuclear holocaust. He suggests that the crucial question human beings are faced with in dealing with the technology is whether to preserve human species and other life forms as they exist or to forge ahead on a mass program of biological reengineering.¹⁸ In “Algeny,” Rifkin attempts to elucidate the social underpinnings of Darwin’s theory of evolution, arguing that the theory is more an attempt to make sense of the social changes resulting from the advent of the Industrial Age than a reflection of scientific truth. In this book, Rifkin draws parallels between Darwinism and what he perceives to be a new view of the world as proposed by scientists of the genetic engineering era.¹⁹ In “Biosphere Politics,” he explores how the last five centuries of human history have shaped our relationship to the natural world.²⁰ In “The Biotech Century,” he attempts to draw parallels between the bioscientific and informational technologies. He predicted that the next century will see the emergence of technological advances that combine computer technology and biological properties; Rifkin views this as portending an era of unprecedented changes to how humans view themselves and the world around them. While the views he expounds in his books are not without their detractors²¹, it is clear that through his books he has sought to reach the public with the philosophical underpinnings of his objection to technology, specifically biotechnology.²²

Rifkin's Motivation for Opposing Biotechnology

The unifying principle in the vast and diverse philosophical motivations driving Jeremy Rifkin's opposition to biotechnology seems to be "fear" of unknown risks. Rifkin has been opposed to biotechnology for a long time (~20 years). Over this period, biotechnology has seen unprecedented and rapid development. Because of this, it is difficult to pinpoint precisely what motivated Rifkin at each of the time points when he was most publicly and vigorously opposed to particular biotechnology events. Moreover, he has expressed conflicting expectations from his efforts, and his views and concerns have likely evolved over time. Nonetheless, broadly speaking, his motivations appear to be premised in fear of several distinct consequences he expects to result from the technology of genetic engineering.

First, Rifkin seems motivated by fears of the technology itself. He believes the new genetic science to be unlike any other technology the history of humankind has ever seen, in that it is capable of raising more troubling issues than previous technologies ever did. This belief evidently arises from his conviction that genetic engineering technology is uniquely capable of altering life, and indeed provides a tool for creating life itself.²³ No other previous technology portends this power.

Second, following from the all-powerful capability provided by this technology, Rifkin fears that one particularly costly price of utilizing this technology is the evisceration of human self-definition. He believes that the ability to manipulate our own genetic code represents the "ultimate expression of human control" in that it enables human beings to determine how they want to be.²⁴ It appears that his main concern is the erosion of the precision of the definition of the term "human," because if humans can cause deliberate alteration to how they are constituted, it would no longer be clear what a human actually is.

Third, driving Rifkin's fear of the loss of human self-definition is his rather negative view of human nature. In his view, all humans have an innate desire to change themselves from their existing manifestation. In this regard, he views genetic engineering as a "[representation of] our fondest hopes and aspirations as well as our darkest fears and misgivings." Indeed, genetic engineering are "dream tools" that grant us the power to transform our vision of ourselves and our descendants.²⁵ It is not clear, however, how he can be confident in this particular conclusion about humanity. It may be that he is driven by a particularly pessimistic view of human self-conception. A more cynical interpretation is that he believes he is endowed with a prescient insight into the human psyche, and consequently bears the responsibility to protect humanity from itself.

RIFKINS EFFORTS AGAINST RECOMBINANT DNA RESEARCH

A. AT THE RAC – RULE AND POLICY MAKING

In 1984, Jeremy Rifkin submitted a groundbreaking proposal to the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health.⁵⁴ This proposal was subsequently debated at a RAC meeting on October 29, 1984. At this meeting, Rifkin had the opportunity to debate his proposal with RAC members.⁵⁵ The juxtaposition of his position against that of scientists as elaborated in letter comments and statements made by RAC members provided an illuminating glimpse into Rifkin's rationale for opposing genetic engineering. This proposal represented one his earliest significant efforts to thwart the progress of genetic engineering technology.

The proposal

In response to NIH and NSF-funded experiments (performed by Ralph Brinster at the University of Pennsylvania) in which human genes regulating the growth hormone were being injected into sheep and pig embryos for the express purpose of incorporating the human genes permanently into the germ line of these mammalian animals, Rifkin proposed an amendment to the NIH guidelines for recombinant DNA experiment. He claimed that the germline transfer experiments represented only the second time in history that a portion of the genetic complement of humans was being transferred into the genetic code of another species.⁵⁶ He proposed that the NIH prohibit any experimentation involving the transfer of a genetic trait from one mammalian species into the germ line of another unrelated mammalian species; “unrelated” was to be defined as any two species that cannot mate and produce one generation of offspring either in the wild or under pre-existing domestic breeding programs. The guideline was to encompass all mammalian species, including homo sapiens. The agency was immediately to discontinue funding all experimental research involving the transfer of genetic traits from one mammalian species into the germ line of another unrelated mammalian species and must instruct all institutions receiving NIH grants that any such experimentation using private funds would be grounds for the immediate suspension of all NIH research grants to the institution. In addition, all private companies signatory to license agreements with NIH-funded institutions were to be bound by the NIH prohibition as well.⁵⁷

Rifkin’s stated purpose for the prohibition was the protection of the biological integrity of every mammalian species, which, in his opinion, was a goal already reflected in the policy underlying many then-existing federal statutes.⁵⁸ He argued that crossing of species borders and incorporating genetic traits from one species directly into the germ line of another represent a fundamental assault on principles of species integrity and constitute a violation of every species’ right to exist as a distinct creature.⁵⁹

Rifkin further argued for symmetrical treatment of human and non-human species. He claimed that since most human beings would condemn attempts to introduce animal genes permanently into the germ line of humans as a “gross and unconscionable” breach of our telos as a species, his proposal would establish the counterpart principle that experiments involving transfer of foreign genes into non-human species would violate the telos of the transferee species, and would therefore be “morally reprehensible.”⁶⁰

Not wishing to stop at mammalian species, he wanted the same principle of species integrity to apply to non-mammalian species as well. Therefore he asked that the RAC establish a working sub-group to propose

Response to Proposal

Prior to the RAC meeting, a total of 359 letters with 433 signatures opposing Rifkin's proposal were received from the general public, scientists and organizations. One letter with 1 signature supported it. These letter comments and the comments of RAC members in response to the proposal were directed at several distinct issues.⁶⁹

There was great concern that important medical research should not be impeded. Commenters suggested that the proposal would cause the discontinuance of important medical research relating to genetic disorders, cancer and other diseases, and thus limit the search for a cure for genetic problems. Some pointed out that there was a need for people born with good health to help those less blessed than they were, and one way to help would be through research. Others pointed out that the proposal would prevent patients with autoimmune and genetic diseases from availing themselves of treatment (presumable involving gene therapy) down the line when future understanding showed safe ways to prevent such sufferings and loss of life.⁷⁰ Still others noted that since knowledge from medical research is valuable to society, any prohibition required substantial justification, which was deemed lacking in the proposal.⁷¹ It was pointed out that animal experimentation necessarily precedes human trials for any kind of gene therapy treatments.⁷² One even went so far as to declare that the practical benefits of the type of research covered by the proposal were so unquestionable and irrefutable that it was absurd even to consider that they should be outweighed by the "putative discomfort to a small number of laboratory animals."⁷³

Interspecies genetic transfer is an important medical research tool. It was pointed out that only when a gene is injected into germ cells can the effect of the gene be seen in an entire organism, and only when a human gene has been injected into another mammal can the embryological actions of a human gene be elucidated. This is because such transfers are often a necessary part of protocols designed to understand how inserted genes behave in host organisms; if the gene is not foreign to the host species, its activity cannot be distinguished from that of the host.⁷⁴ Indeed, interspecies gene transfer experiments were the only means available at the time for studying gene regulation and the development of complex systems such as animals and humans.⁷⁵

It was asserted that the American public wanted genetic engineering research to continue. A number of RAC members pointed to the overwhelming public response to the proposal. One suggested that the American public had expressed its view on the subject, calling attention to the several hundred letters from individuals

Rifkin's Response

In response to a motion for the RAC to reject the proposal, Rifkin sounded a rare conciliatory tone. He acknowledged that RAC members were well-intentioned, for they would not be part of the medical research community if they did not think they were trying to improve the welfare of humanity.⁹⁰ He empathized with the difficulty for any profession to critique itself, but asked the members to examine their world view before making any “hasty” decisions. He suggested that they re-evaluate their modern science assumptions and consider that other people may not share their world view.⁹¹

He went on to reiterate his belief that the technology at hand was so powerful that the consequences and risks had to be acknowledged, lest the costs be heaped on the ecosystem and future generations. He implied that it was either naïve or disingenuous to believe there were no risks and no costs associated with the biotechnology revolution. He felt it unreasonable that the scientific community should be given full license at every juncture to pursue any kind of research in any area. In response to RAC members' argument that impeding biotechnology research would lead to continued human suffering, he argued that such an assertion suggested a syndrome of fear. He questioned how RAC could “prematurely” conclude that the long-term benefits outweighed the risks when only a few gene transfer experiments had been carried out. He asked for a moratorium on this type of research until a time when the relevant questions were being properly addressed by the American public.⁹²

On a final note, Rifkin suggested that the letters that had been received and quoted by the committee on his proposal were not representative of an accurate cross-section of the American public.⁹³ Thus, he implicitly held onto his belief that his views were the more reflective of those of the masses.

RAC's counter-response

The committee bristled at Rifkin's characterization of their attitude toward gene transfer experimentation. They first suggested that Rifkin had either misunderstood or misconstrued their comments. They maintained that rather than suggesting there were no problems associated with the experiments in question, they were merely following an orderly process of consistently exercising care and prudence in approaching the utilization of recombinant DNA technology. Moreover, they insisted that most of them had not spent just "one hour" considering the issues at hand, as Rifkin had suggested, but rather had been thinking about them for years. It was simply that they recognized there were risks associated with any new technology, and that a total prohibition would prevent their ever learning whether the potential risks were real or mythical.⁹⁴

Moreover, they argued that total prohibition in the United States would not stop such research from being performed elsewhere. Such attempts at prohibition had not apparently ever worked, and thus the RAC should continue to evaluate such experiments, so as to allow the United States Government to maintain its control over them.⁹⁵

The RAC refuted Rifkin's contention that its world view consisted only of seeing the benefits of biotechnology whereas he was singularly willing to point out the potential risks. On the contrary, one member said, the difference between Rifkin and the RAC was that, seeing both the risks and benefits, Rifkin chose to prohibit seeking the benefits whereas the RAC would prefer to continue with maximizing benefits while minimizing risks.⁹⁶ Another member wondered how a social problem (risk) could be successfully solved before the technological means was developed to address it.⁹⁷

Finally, one RAC member expressed frustration with Rifkin's insatiable appetite for opposing biotechnology research. The member noted that as soon as one his concerns was allayed, another concern surfaced. He suggested that Rifkin was attempting to arrest a process that had been spectacularly successful.⁹⁸

Outcome

The RAC voted down the proposal by a unanimous vote.

B. LAWSUIT

Failing to persuade the NIH to change its stance on genetic transfer research, Rifkin, through FET, filed a lawsuit to enjoin research of this nature. The defendant in this suit was the USDA because of its funding and facility support for the experiments.⁹⁹

*Foundation on Economic Trends v. Block*¹⁰⁰ – The “Animal Productivity Research” Case – District Court

The plaintiffs claimed that the USDA violated the NEPA by failing to prepare an environmental impact statement on its animal productivity research, which included the very genetic transfer experiments being performed by Ralph Brinster that had instigated Rifkin’s proposal for prohibiting NIH support for such research.¹⁰¹ They argued that the USDA’s decision to focus its animal productivity research on developing faster growing, more productive, and larger animals required an analysis of the resulting environmental impacts, and thus an impact statement was necessary and should have been considered in the development of the USDA research program. The complaint alleged that the USDA’s research program had or would have significant environmental, economic, and social impact through forcing dislocations in the farm economy, affecting the gene pool of farm and food animals, and polluting the air and water. The plaintiffs sought declaratory relief that the USDA had violated the NEPA¹⁰² by preparing neither an environmental assessment nor an environmental impact statement¹⁰³ in connection with its research program (which included recombinant DNA experiments). They also sought a finding against the defendants for violation of the Administrative Procedures Act through acting arbitrarily and capriciously in not considering alternatives to its research programs for improving animal productivity.¹⁰⁴

The Court concluded that the USDA's research activities did not constitute a "proposal for legislation or other major Federal action significantly affecting the environment," and therefore neither an environmental assessment nor impact statement was required. It granted summary judgment to the defendants.¹⁰⁵

*Foundation on Economic Trends v. Lyng*¹⁰⁶ – The "Animal Productivity Research" Case – Appellate Court

The Appellate Court affirmed the lower court's summary judgment, but on different grounds. It found no need to determine whether the USDA program posed a significant impact to the environment because it did not even constitute a proposal for action that required an NEPA impact statement. It further noted that the plaintiffs' real objection related to the objectives of the scientific research being performed by the USDA.¹⁰⁷ It concluded this to be the case despite the plaintiffs' insistence that they were not objecting to selective breeding technologies per se, nor to pathbreaking research projects involving the use of recombinant DNA techniques, but rather were simply saying that an impact statement was required to evaluate the goals of animal productivity research that is focused on developing faster growing, more productive, and larger animals.¹⁰⁸ It is tempting to speculate that the Court was wary of the plaintiffs' real objectives in filing the lawsuit: to use procedural maneuvers to block all biotechnology research.

B.

From the mid-1980's to the 1990s, Rifkin filed a series of legal challenges against the USDA, NIH and EPA (and later the FDA) actions that directly or indirectly related to biotechnology.

The motivating factor for these lawsuits, in his own words, was that federal regulators were not interested in listening to his viewpoint until “[the] interest [was framed] by forcing public policy to deal with court decisions.” Underlying this cynical view of the federal authorities was his belief that the government was simply not ready (or willing) to regulate biotechnology.¹⁰⁹ Relatedly, he felt that the lawsuits would serve as “educational tools to get discussions [about assumptions and intentions underlying biotechnology] going... before the technology [came] on line.” Perhaps most importantly, as some would argue, he knew the lawsuits “[drove the] industry nuts.”¹¹⁰

Not surprisingly, advocates of biotechnology did not have a charitable view of Rifkin’s motivations for the legal challenges. They believed that Rifkin, after having failed “to intimidate” the NIH into prohibiting genetic engineering research, had decided to turn to the EPA and USDA, which are softer targets by virtue of being more politically vulnerable. They suspected that Rifkin’s lawsuits (based always on procedural technicalities) were motivated by a broader purpose, namely to engage in “a war against all genetic engineering,” rather than seeking merely to ensure that scientists not ignore federal biotechnology regulations.¹¹¹

Cases involving “Deliberate release of genetically engineered organisms”

*Foundation on Economic Trends v. Heckler*¹¹² – District Court

This case arose from the NIH’s decision to permit the first government-approved release of a genetically engineered organism into the environment. In the early 1980s, University of California researchers modified a bacterium that in its naturally-occurring state has the ability to nucleate ice crystals. The modification, achieved through recombinant DNA technology, resulted in deletion of the genetic code that normally confers the bacterium’s ice-making trait. Upon approval of a field test of the modified bacteria involving its deliberate release into the environment, Jeremy Rifkin, through the FET, filed for an injunction against the experiment until such time as the NIH had conducted and published an environmental impact statement.¹¹³

The District Court addressed the plaintiffs’ complaint that the NIH had failed to issue appropriate environmental impact statements as required by NEPA and in conformity with the regulations of the Council on Environmental Quality.¹¹⁴ The gist of the plaintiffs’ complaint was that a revision of NIH Guidelines in 1978 to permit deliberate release experiments and the authorization of such experiments constituted a “major federal action.” It deemed NIH’s failure to precede the action with a documented “hard look” at the environmental implications of that action to be tantamount to an NEPA violation.¹¹⁵ In deciding whether there was a likelihood of plaintiffs succeeding on the merits, the Court concluded affirmatively on all three issues before it. It found that the NIH had not fulfilled its NEPA obligations when it failed to (1) issue an environmental impact statement for its 1978 revision to the NIH Guidelines which provided authority to permit deliberate-release experimentation by NIH grantees;¹¹⁶ (2) issue any broad, programmatic environmental impact statement¹¹⁷ addressing the general environmental issues presented in NIH approval of deliberate release experiments; and (3) issue an environmental assessment or an environmental impact statement addressing the specific environmental issues associated with the first deliberate release experiment to be conducted under the 1978 revised NIH Guidelines. Consequently, the Court granted a preliminary injunction against the NIH from approving or continuing to approve experiments involving deliberate release of recombinant DNA organisms. It also enjoined the University of California from proceeding with the deliberate release experiment that the NIH had approved.¹¹⁸

*Foundation on Economic Trends v. Heckler*¹¹⁹ – Appellate Court

The decision of the District Court was appealed to the U. S. Court of Appeals of the District of Columbia Circuit. The Appellate Court affirmed in part and reversed in part.

The Court affirmed the lower court's injunction against the University of California experiment. In holding so, it went to some length to emphasize its concern about the environmental risks that may result from such experiments (although it did refrain from explicitly saying that it believed there was a likelihood of these risks materializing). It implored the NIH to attempt to evaluate seriously the risk that emigration of the genetically engineered organisms from test sites would cause ecological disruption, and suggested that until such an evaluation was completed, the questions of whether an environmental impact statement was required would remain open. It pointed out that one criterion for determining whether such a statement was required was "the degree to which possible effects on the human environment are highly uncertain or involve unique or unknown risks."¹²⁰ Thus, the Court here was quite explicitly in agreement with Rifkin's concerns.

On the other hand, the Court vacated the lower court's injunction against NIH's approval of *all* deliberate release experiments. It found that the district court's focus on the 1978 NIH Guidelines revision as a basis for an injunction and requiring an environmental impact statement was inappropriate. It further found that, while it thought a programmatic statement would be helpful, it was not certain as a matter of law that plaintiffs would succeed in showing that the absence of a programmatic statement was a violation of the NEPA and the Council on Environmental Quality's regulations.¹²¹

Unfortunately for Rifkin, he was excoriated in the concurring opinion. The concurring judge stated that the plaintiffs should have brought its original concerns directly to the NIH. He noted that the Court would "undoubtedly have had a better record [available to it in the case] if the Foundation on Economic Trends had not failed to raise its objections while the matter was pending before the [NIH]." He pointed out that public comments were solicited through the Federal Register, but none were forthcoming from the FET. He conjectured that had the FET voiced its objections to the NIH, it was more than likely, "given the demonstrated sensitivity of NIH and its scientists to such matters," the defendants would have responded to any objections. He further blamed the FET's conduct for delaying¹⁸ the vital experiments in question for "a very considerable period of time," and submitted that "the use of delaying tactics by those who fear and oppose scientific progress [was] nothing new." Furthermore, the judge worried that a "national catastrophe" would result should the development of the promising technology of genetic engineering be "crippled by the unconscionable delays...

The Court ruled against the plaintiffs on the ground that they had not identified any proposals for major federal action significantly affecting the quality of the human environment for which the NEPA would require an impact statement.¹⁴⁰

*Foundation on Economic Trends v. Lyng*¹⁴¹ – The “USDA Germplasm” Case – Appellate Court

On appeal, the Court affirmed the lower court’s decision on a procedural ground. Instead of deciding on the merits, as the District Court had done, it found that the plaintiffs lacked standing to sue. The plaintiffs had claimed “informational standing,” which was a broadly-defined basis for standing that in some cases had been available to organizations engaged in disseminating environmental information.¹⁴² Fearing that allowing broad availability of informational standing would eliminate any standing requirement at all in NEPA cases, the Court held that alleging “information” injury without identifying a particular agency action as the source of the injury is insufficient to gain informational standing. In this case, the Court found that the plaintiffs had failed to identify an agency action amounting to a “major federal action” in the USDA’s germplasm activities.¹⁴³ Thus, while basing its holding on a procedural (standing) ground, the Court in fact also addressed the issue of merit on which the lower court had ruled against the plaintiffs. This decision was more damaging to the plaintiffs than it would initially appear, because by dismissing the case on the technical ground of standing, the Court appeared to be signaling that it wished henceforth to restrict access by such plaintiffs to the courts for litigation of similar issues on which the plaintiffs had previously been successful (*see e.g., supra, Foundation on Economic Trends v. Heckler*).¹⁴⁴ Indeed, there is supporting language in the opinion alluding to just such an intention; the Court noted with approval the lower court’s contention that the plaintiffs were seeking “judicial involvement in day-to-day decision-making of the USDA.”¹⁴⁵

*Foundation on Economic Trends v. Weinberger*¹⁴⁶

The plaintiffs sought to enjoin the construction of a proposed “Aerosol Test Facility” and “Toxic Agent Test Support Facilities” by the Department of the Army. They contended that the defendants had failed to comply with NEPA requirements by failing to prepare an environmental impact statement. The defendants argued that such a statement was not required under the circumstances because they had made a legally adequate and factually supported finding of no significant environmental impact (in an environmental assessment).¹⁴⁷ The plaintiffs contended that, contrary to the defendants’ disclaimers, recombinant research geared towards biological warfare would be performed at the proposed new facilities.¹⁴⁸ In their view, recombinant DNA research is precisely the type of “new and expanding technological advances” that concerned the drafters of the NEPA. Therefore, the scope of the proposed federal action was in fact broader than that which the Army had contemplated in its assessment finding no significant environmental impact (and hence no requirement for an

First, he argued that the experience in the single area in which Congress had specifically authorized the patenting of living organisms, namely through the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, showed that the patenting of any life form necessarily led to genetic and social impacts that were contrary to the society's best interests. In support of this contention, he stated that plant patents had led to the systematic elimination of many plant and crop varieties that were not patentable by virtue of being merely products of nature; with the loss of genetic diversity, monoculturing becomes the dominant reality. Moreover, plant breeding had become such a lucrative endeavor that there was an increasing concentration of basic plant food supply ownership in the hands of a small number of large multinational corporations.¹⁵⁶

Second, he contended that the technology of genetic engineering, taken as a whole, was not in the public interest. Pointing to the unknown and potential risks of biotechnology, he argued that the public interest would be endangered by the “[irreversible pollution of] the planetary gene pool in radically new ways” as a result of the proliferation of genetic engineering techniques and novel life forms.¹⁵⁷

Third, he argued that the patenting of lower organisms would invariably lead to the patenting of higher forms of life. In support of this argument, he reasoned that recombinant DNA techniques will eventually lead to genetic engineering of higher life forms (than bacteria), including humans, for which patenting will have to be allowed based on the same rationale for allowing patenting of the bacterium in this case. This, he pointed out, would raise moral and ethical issues involving a determination of “the very nature of life” itself.¹⁵⁸

The Supreme Court ultimately held, by a 5-4 vote, to allow the patenting of the bacterium. Even so, Rifkin drew solace in the observation that the justices viewed their decision as a narrowly construed one. He noted Justice Burger's reference to "the gruesome parade of horrors" outlined in his amicus brief as the latter explained that the Court's decision was based on a logical interpretation of existing patent law and was not intended to address the larger social issues surrounding the genetic engineering of life.¹⁵⁹

Out-of-Court Opposition

Besides participating in legal challenges to the patenting of genetically engineered life forms, Rifkin was also responsible for assembling major coalitions aimed at drawing attention to the issuing of such patents. In May of 1994, a coalition of hundreds of women's organizations from more than forty nations announced their collective opposition to the attempt by Myriad Genetics, a U.S. biotechnology company, to patent the discovery of a breast cancer gene. The next year, Rifkin organized a coalition of more than two hundred religious leaders, from a broad range of denominations and faiths, which announced its opposition to the granting of patents on animal and human genes, organs, tissues and organisms.¹⁶⁰

RIFKIN'S EFFORTS AGAINST BIOTECHNOLOGY PRODUCTS

A.

On November 5, 1993, the FDA approved the use of a genetically engineered form of a bovine growth hormone (rBST) in dairy cows. This event sparked a series of high-profile protests that eventually culminated in court challenges. By this time, Rifkin's reputation as an anti-biotechnology activist was well-established. Not surprisingly, he immediately galvanized a broad grass-roots campaign to oppose rBST. rBST represented the culmination of the technology of genetic engineering in that it was the first genetically engineered product to be commercially marketed. It thus represented the end product of the process the progress of which Rifkin had been fighting to block throughout the previous decade.

rBST, the acronym for recombinant bovine somatotropin, is the genetically engineered version of bovine growth hormone, which is a naturally occurring protein that cows ordinarily produce to direct nutrients toward milk production.¹⁶¹ Prior to the arrival of genetic engineering techniques, the process of administering the hormone to cows to induce lactation relied on injecting growth hormone-containing tissue extracts from dead cows into live cows. The inefficiency of this method precluded large-scale commercial use of the hormone.¹⁶² The arrival of biotechnology changed this situation; genetic engineering techniques allowed for easy and mass production of purified rBST that appeared to function similarly as natural BST.¹⁶³ Among the four major U.S. corporations that competed in the 1980s to develop recombinant BST, Monsanto was the eventual victor, after investing \$800 million in product development alone.¹⁶⁴ Monsanto's rBST, Posilac, reportedly yielded a 15% to 25% increase in milk production.¹⁶⁵

The FDA began its review of the safety and efficacy of rBST in 1984,¹⁶⁶ and finally approved its use in commercial applications on November 12, 1993, after over 120 studies had been evaluated. It declared that milk from treated cows was indistinguishable from milk from untreated cows, and therefore would not have to be labeled.¹⁶⁷ Congress accepted the FDA judgment in full.¹⁶⁸ Milk, thus, became the first food that the U.S. Government allowed to be produced using a genetically engineered drug.

The FDA subsequently issued interim guidelines warning producers who label milk as coming from untreated cows to ensure that those labels were neither false nor misleading. It reasoned that since all milk contains natural BST, labels that said "BST-free" would be false and potentially misleading. Whether a label would be false or misleading would be largely dependent on the context within which terms such as "BST-free" appear on the label. Thus, the FDA guidelines suggested that labels indicating milk from untreated cows also include disclaimers that state, for instance, that "no significant difference has been shown between milk from

B.

In May, 1992, the FDA published a statement of policy for foods derived from new plant varieties, which included plants developed by recombinant DNA techniques.²⁰⁸ It decreed that it would not require pre-market approval of genetically altered food.²⁰⁹ It also said it would not require food developed using recombinant DNA techniques to bear special labeling to reveal that fact to consumers; it believed the new techniques were merely extensions at the molecular level of traditional methods and would be used to achieve the same goals as pursued with traditional plant breeding.²¹⁰ About 3,000 letters of opposition, many from members of the Pure Food Campaign, were submitted to the FDA in response to this statement of policy.²¹¹ Rifkin and his organization also filed a petition with the FDA to require testing and labeling of genetically engineered foods.²¹² In spite of this, the FDA maintained the position it had adopted in the policy statement.

The FDA's approval of Calgene, Inc.'s informal request to market its Flavr Savr tomato, which had been genetically altered to achieve longer-lasting shelf life, was greeted with activist outcry. Rifkin called it "an untested potential threat to the nation's health."²¹³ He once again demanded the tomato be labeled to indicate that it was genetically engineered.²¹⁴

Rifkin expressed several concerns regarding the commercial sale of genetically engineered *foods*, of which the Calgene tomato was the first (rBST was a *drug*, and the milk from rBST cows was not actually genetically altered). His concerns were premised upon the same environmental and ethical concerns he had expressed all along in opposing biotechnology. These concerns were not allayed by the reassurances and counterarguments of the FDA and other scientists.²¹⁵

First, he argued that since genetically engineered food products are alive, they are unpredictable, being capable of reproducing, mutating and migrating once released into the environment. He feared that the long-term cumulative impact on the environment from the release of thousands of such products would be devastating.²¹⁶ Calgene's tomato would merely be the first of these products.

Second, the genetic transfer of genes that result in the development of products such as the Flavr Savr tomato involves the crossing of species boundaries. This, he believed, went far beyond traditional breeding techniques. To him, it represented the "ultimate offense to²⁵ the dignity and integrity of the biotic community."²¹⁷

Third, without labeling of genetically engineered foods, consumers would not be able to make an informed choice when purchasing their foods. In one of its handouts, the Pure Food Campaign warned consumers that unprecedented genetic combinations, including cantaloupe and yellow squash containing bacteria and virus

The public opposition to the pioneering biotechnology products may have resulted in the curtailment of the industry's development and introduction of similar commercial biotechnology products. Genetically engineered food products have accounted for only a tiny percentage of biotechnology products that have entered the marketplace since the Calgene tomato. In 1997, less than 5 percent of biotechnology products was genetically engineered foods, with the rest being crop protection products.²³⁶ This trend suggests that while industry interest in genetic engineering of commercial goods such as agricultural protection products has persisted, there has not been as much progress on the food product front. It is reasonable to conclude that had rBST and Flavr Savr been greeted with a more positive market response, the industry would have jumped on the bandwagon to develop and commercialize other genetically engineered foods.

Also, Rifkin's efforts ultimately hurt the cause of biotechnology in a manner that would result in the most damage, namely through calling into question in the public eye the credibility of the FDA. The FDA, as the nation's arbiter of what foods and drugs are safe and effective for the consumption of Americans, serves as the gatekeeper for biotechnology products seeking entry into the American marketplace. And its function in this regard is tremendously dependent on the American public's confidence in its effectiveness in keeping out harmful products. The onslaught of extremely negative publicity, and the accompanying public denunciation and boycott of rBST/rBST milk and the Calgene tomato, all of which were biotechnology products that had been certified safe by the FDA, tarnished the image and credibility of the FDA, in general, and specifically in relation to biotechnology products. Thus, Rifkin's efforts succeeded in wresting away the one legitimizing stamp of approval the industry had for its products.

Nonetheless, even Rifkin must realize that biotechnology is here to stay and that discrediting federal agencies, such as the FDA, that are entrusted with serving the public good, is not the most beneficial outcome for the American public in the long run. As such, it is important to recognize that there are aspects of their activities that Rifkin and his fellow activists could have done differently that might have led to a more constructive overall outcome in the whole biotechnology debate.

It is important that Rifkin recognize that hyperbole and doomsday-type sound bites do not belong in debates with individuals whose vocation is by definition steeped in the *objective* realm of science. Officials at federal agencies like the FDA, the NIH and in the biotechnology industry are trained to make decisions based on the scientific method. Rifkin's habit was ineffective with, and apparently infuriating to, these people, and all the more so because they believed that he was effectively misleading the public. Under these antagonistic circumstances, it is no wonder that neither side was willing to "listen" to the other.

Rifkin should have realized that his insistence on total abolition of biotechnology was untenable. First, even if biotechnology were stopped in the U.S., it would continue elsewhere in the world. And, as he himself has pointed out, one of the distinctive dangers of genetically engineered entities is their potential for wreaking havoc with the environment, which is a parameter that recognizes no geopolitical boundaries. Second, his basis for banning the technology, which is the potential risks associated with it, is antithetical to the experience with and premise of all technological advances. All new technologies have inherent uncertainties, and this is a reality that the FDA recognized when it promulgated its policy on foods derived from processes involving recombinant DNA.²³⁷ Thus, unless Rifkin had proposed an alternative path by which society could continually better its condition without accessing new technology, it would have been impossible, even arguably unconscionable, to abandon promising advances such as biotechnology.

If Rifkin had recognized that biotechnology was here to stay, he could have chosen to *participate* in efforts to ensure the safest implementation possible of the technology, rather than continuing a vain effort to obstruct it. In this regard, Rifkin should have abandoned the strategy of engaging in procedural maneuvers aimed at blocking the technology under the guise of ensuring proper adherence to regulatory technicalities. For example, most of his lawsuits involved claims that federal agencies (e.g. FDA for rBST, USDA for deliberate release experiments) acted arbitrarily and capriciously in arriving at their decisions and that they violated the NEPA in their environmental impact considerations. While these are important issues (certainly in the case of envi-

